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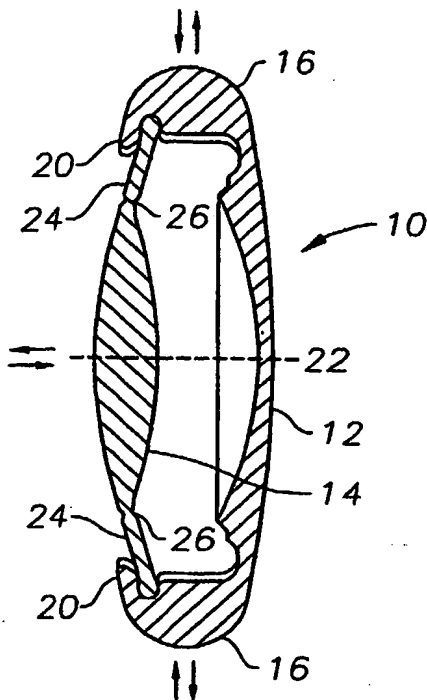
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ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: ACCOMMODATIVE INTRAOCULAR LENS



(57) Abstract: A two-optic accommodative lens system. The first lens (12) has a negative power and is located posteriorly against the posterior capsule. The periphery of the first optic contains a pair of clasps (16). The second optic (14) is located anteriorly to the first optic (12) and is of a positive power. The peripheral edge of the second optic contains a pair of locking arms that fit into the clasps (16) contained on the periphery of the first optic to lock the second optic onto the first optic, but allow for rotation of the arms within the clasps. Hinge structures (18) on the locking arms allow the second optic to move relative to the first optic along the optical axis of the lens system in reaction to movement of the ciliary muscle.

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ACCOMMODATIVE INTRAOCULAR LENS

Background of the Invention

This invention relates generally to the field of intraocular lenses (IOL) and, more particularly, to accommodative IOLs.

5 The human eye in its simplest terms functions to provide vision by transmitting light through a clear outer portion called the cornea, and focusing the image by way of a crystalline lens onto a retina. The quality of the focused image depends on many factors including the size and shape of the eye, and the transparency of the cornea and the lens.

10 When age or disease causes the lens to become less transparent, vision deteriorates because of the diminished light which can be transmitted to the retina. This deficiency in the lens of the eye is medically known as a cataract. An accepted treatment for this condition is surgical removal of the lens and replacement of the lens function by an artificial intraocular lens (IOL).

15 In the United States, the majority of cataractous lenses are removed by a surgical technique called phacoemulsification. During this procedure, an opening is made in the anterior capsule and a thin phacoemulsification cutting tip is inserted into the diseased lens and vibrated ultrasonically. The vibrating cutting tip liquifies or emulsifies the lens so that the lens may be aspirated out of the eye. The diseased lens, once removed, is replaced by an artificial lens.

20 In the natural lens, bifocality of distance and near vision is provided by a mechanism known as accommodation. The natural lens, early in life, is soft and contained within the capsular bag. The bag is suspended from the ciliary muscle by the zonules. Relaxation of the ciliary muscle tightens the zonules, and stretches the capsular bag. As a result, the natural lens tends to flatten. Tightening of the ciliary muscle relaxes the
25 tension on the zonules, allowing the capsular bag and the natural lens to assume a more rounded shape. In the way, the natural lens can be focus alternatively on near and far objects.

30 As the lens ages, it becomes harder and is less able to change shape in reaction to the tightening of the ciliary muscle. This makes it harder for the lens to focus on near objects, a medical condition known as presbyopia. Presbyopia affects nearly all adults over the age of 45 or 50.

Prior to the present invention, when a cataract or other disease required the removal of the natural lens and replacement with an artificial IOL, the IOL was a monofocal lens, requiring that the patient use a pair of spectacles or contact lenses for near vision. Allergan has been selling an bifocal IOL, the Array lens, for several years, but due to quality of issues, this lens has not been widely accepted.

Several designs for accommodative IOLs are being studied. For example, several designs manufactured by C&C Vision are currently undergoing clinical trials. See U.S. Patent Nos. 6,197,059, 5,674,282, 5,496,366 and 5,476,514 (Cumming), the entire contents of which being incorporated herein by reference. The lens described in these patents is a single optic lens having flexible haptics that allows the optic to move forward and backward in reaction to movement of the ciliary muscle. A similar designs are described in U.S. Patent No. 6,302,911 B1 (Hanna), 6,261,321 B1 and 6,241,777 B1 (both to Kellan), the entire contents of which being incorporated herein by reference. The amount of movement of the optic in these single-lens systems, however, may be insufficient to allow for a useful range of accommodation. In addition, as described in U.S. Patent Nos. 6,197,059, 5,674,282, 5,496,366 and 5,476,514, the eye must be paralyzed for one to two weeks in order for capsular fibrosis to entrap the lens that thereby provide for a rigid association between the lens and the capsular bag. In addition, the commercial models of these lenses are made from a hydrogel or silicone material. Such materials are not inherently resistive to the formation of posterior capsule opacification ("PCO"). The only treatment for PCO is a capsulotomy using a Nd:YAG laser that vaporizes a portion of the posterior capsule. Such destruction of the posterior capsule may destroy the mechanism of accommodation of these lenses.

There have been some attempts to make a two-optic accommodative lens system. For example, U.S. Patent No. 5,275,623 (Sarfarazi), WIPO Publication No. 00/66037 (Glick, et al.) and WO 01/34067 A1 (Bandhauer, et al), the entire contents of which being incorporated herein by reference, all disclose a two-optic lens system with one optic having a positive power and the other optic having a negative power. The optics are connected by a hinge mechanism that reacts to movement of the ciliary muscle to move the optics closer together or further apart, thereby providing accommodation. In order to provide this "zoom lens" effect, movement of the ciliary muscle must be adequately transmitted to the lens system through the capsular bag, and none of these references

disclose a mechanism for ensuring that there is a tight connection between the capsular bag and the lens system. In addition, none of these lenses designs have addressed the problem with PCO noted above.

Therefore, a need continues to exist for a safe and stable accommodative intraocular lens system that provides accommodation over a broad and useful range.

Brief Summary of the Invention

The present invention improves upon the prior art by providing a two-optic accommodative lens system. The first lens has a negative power and is located posteriorly against the posterior capsule. The periphery of the first optic contains a pair of clasps. The second optic is located anteriorly to the first optic and is of a positive power. The peripheral edge of the second optic contains a pair of locking arms that fit into the clasps contained on the periphery of the first optic to lock the second optic onto the first optic, but allow for rotation of the arms within the clasps. Hinge structures on the locking arms allow the second optic to move relative to the first optic along the optical axis of the lens system in reaction to movement of the ciliary muscle.

Accordingly, one objective of the present invention is to provide a safe and biocompatible intraocular lens.

Another objective of the present invention is to provide a safe and biocompatible intraocular lens that is easily implanted in the posterior chamber.

Still another objective of the present invention is to provide a safe and biocompatible intraocular lens that is stable in the posterior chamber.

Still another objective of the present invention is to provide a safe and biocompatible accommodative lens system.

These and other advantages and objectives of the present invention will become apparent from the detailed description and claims that follow.

Brief Description of the Drawing

FIG. 1 is an enlarged top plan view of the first optic of a first embodiment of the lens system of the present invention.

FIG. 2 is an enlarged cross-sectional view of the first optic of a first embodiment of the lens system of the present invention taken at line 2-2 in FIG. 1.

FIG. 3 is an enlarged top plan view of the second optic of a first embodiment of the lens system of the present invention.

FIG. 4 is an enlarged cross-sectional view of the second optic of a first embodiment of the lens system of the present invention taken at line 4-4 in FIG. 3.

FIG. 5 is an enlarged partial cross-sectional view taken at circle 5 in FIG. 4.

FIG. 6 is an enlarged top plan view of the first optic of a second embodiment of the lens system of the present invention.

FIG. 7 is an enlarged cross-sectional view of the first optic of a second embodiment of the lens system of the present invention taken at line 7-7 in FIG. 6.

FIG. 8 is an enlarged top plan view of the second optic of a second embodiment of the lens system of the present invention.

FIG. 9 is an enlarged cross-sectional view of the second optic of a second embodiment of the lens system of the present invention taken at line 9-9 in FIG. 8.

FIG. 10 is a cross-sectional view of the first embodiment of the lens system of the present invention illustrated in FIGS. 1-5.

FIG. 11 is a cross-sectional view of the second embodiment of the lens system of the present invention illustrated in FIGS. 6-9.

FIG. 12 is a cross-sectional view of the first embodiment of the lens system of the present invention illustrated in FIGS. 1-5 and illustrating the lens system implanted within a capsular bag.

FIG. 13 is a cross-sectional view of the second embodiment of the lens system of the present invention illustrated in FIGS. 6-9 and illustrating the lens system implanted within a capsular bag.

FIG. 14 is an enlarged top plan view of the first optic of a third embodiment of the lens system of the present invention.

FIG. 15 is an enlarged cross-sectional view of the first optic of a third embodiment of the lens system of the present invention taken at line 15-15 in FIG. 14.

FIG. 16 is an enlarged partial cross-sectional view taken at circle 16 in FIG. 15.

FIG. 17 is an enlarged top plan view of the second optic of a third embodiment of the lens system of the present invention.

FIG. 18 is an enlarged cross-sectional view of the second optic of a third embodiment of the lens system of the present invention taken at line 18-18 in FIG. 17.

FIG. 19 is an enlarged partial cross-sectional view taken at circle 19 in FIG. 18.

FIG. 20 is an enlarged top plan view of the third embodiment of the lens system of the present invention illustrated in FIGS. 14-19.

FIG. 21 is a cross-sectional view of the third embodiment of the lens system of the present invention taken at line 21-21 in FIG. 20.

FIG. 22 is an enlarged top plan view of the first optic of a fourth embodiment of the lens system of the present invention.

FIG. 23 is an enlarged cross-sectional view of the first optic of a third embodiment of the lens system of the present invention taken at line 23-23 in FIG. 22.

FIG. 24 is an enlarged top plan view of the second optic of a fourth embodiment of the lens system of the present invention.

FIG. 25 is an enlarged cross-sectional view of the second optic of a third embodiment of the lens system of the present invention taken at line 25-25 in FIG. 24.

FIG. 26 is an enlarged partial cross-sectional view taken at circle 26 in FIG. 25.

FIG. 27 is an enlarged top plan view of the fourth embodiment of the lens system of the present invention illustrated in FIGS. 26-26.

FIG. 28 is a cross-sectional view of the fourth embodiment of the lens system of the present invention taken at line 28-28 in FIG. 27.

Detailed Description of the Invention

As best seen in FIGS. 1-5 and 10, lens system 10 of the present invention generally consists of posterior optic 12 and anterior optic 14. Optic 12 is preferably formed in any suitable overall diameter or length, for example, around 12 millimeters, for implantation in the posterior chamber. Optic 12 preferably is made from a soft, foldable material that is

inherently resistive to the formation of PCO, such as a soft acrylic. Optic 14 preferable is made from a soft, foldable material such as a hydrogel, silicone or soft acrylic. Optic 12 may be any suitable power, but preferably has a negative power. Optic 14 may also be any suitable power but preferably has a positive power. The relative powers of optics 12 and 14 should be such that the axial movement of optic 14 toward or away from optic 12 should be sufficient to adjust the overall power of lens system 10 at least one diopter and preferably, at least three to four diopters, calculation of such powers of optics 12 and 14 being within the capabilities of one skilled in the art of designing ophthalmic lenses by, for example, using the following equations:

$$P = P_1 + P_2 - T/n * P_1 P_2 \quad (1)$$

$$\delta P = \delta T/n * P_1 P_2 \quad (2)$$

As best seen in FIGS. 1 and 2, optic 12 is generally symmetrical about optical axis 22 and contains a pair of opposing clasps 16 that are shaped to stretch and fill equatorial region 210 of capsular bag 200. Clasps 16 contain sockets 18 generally defined by latch 20. As best seen in FIGS. 3-5, optic 14 contains a pair of haptics 24 that are connected to optic 14 by hinge regions 26 and contain locking pins 28 distally from hinge regions 26. As seen in FIG. 10, locking pins 28 are sized and shaped to fit within sockets 18 on optic 12, thereby holding optic 14 firmly within optic 12 while still permitting rotation of locking pins 28 within sockets 18. One skilled in the art will recognize that sockets 18 may be located on hinge regions 26 and that locking pins 28 may be located on optic 12. In order to insert locking pins 28 within sockets 18, sockets 18 may be spread apart slightly, thereby preloading haptics 24. Once implanted in an eye, as one skilled in the art will recognize, contraction of capsular bag 200 will cause clasps 16 to collapse slightly, thereby causing compression of optic 14. As optic 14 is compressed, hinge regions 26 allow optic 14 to vault anteriorly away from optic 12, with locking pins 28 pivoting within sockets 18. One skilled in the art will recognize that no specific feature needs to be used to form hinge regions 26 as haptics 24 may be formed from a material and/or in such a configuration that haptics naturally flex in the manner of a hinge.

As best seen in FIGS. 6-9 and 11, lens system 110 of the present invention generally consisting of posterior optic 112 and anterior optic 114. Optic 112 is preferably

formed in any suitable overall diameter or length, for example, around 12 millimeters, for implantation in the posterior chamber. Optic 112 preferably is made from a soft, foldable material that is inherently resistive to the formation of PCO, such as a soft acrylic. Optic 114 preferable is made from a soft, foldable material such as a hydrogel, silicone or soft acrylic. Optic 112 may be any suitable power, but preferably has a negative power. Optic 114 may also be any suitable power but preferably has a positive power. The relative powers of optics 112 and 114 should be such that the axial movement of optic 114 toward or away from optic 112 should be sufficient to adjust the overall power of lens system at least one diopter and preferably, at least three to four diopters, calculation of such powers of optics 112 and 114 being within the capabilities of one skilled in the art. One skilled in the art will also recognize that the axial movement of optic 114 relative to optic 112 is greater in this embodiment as opposed to the embodiment illustrated in FIGS. 1-5 due to the longer length of haptic 124 versus haptic 24.

As best seen in FIGS. 6, 7 and 13, optic 112 is generally symmetrical about optical axis 122 and contains a pair of opposing clasps 116 that are shaped to stretch and fill equatorial region 310 of capsular bag 300. Clasps 116 contain sockets 118 generally defined by latch 120. As best seen in FIGS. 8 and 9, optic 114 contains circumferential haptic 124 that are connected to optic 114 by hinge regions 126 and contain locking pins 128 distally on the periphery of haptics 124. One skilled in the art will recognize that sockets 118 may be located on clasps 116 and that locking pins 128 may be located on haptics 124. As seen in FIG. 11, locking pins 128 are sized and shaped to fit within sockets 118 on optic 112, thereby holding optic 114 firmly within optic 112 while still permitting rotation of locking pins 128 within sockets 118. Preferably, locking pins 128 are located approximately 90° from hinge regions 126 around the circumference of optic 114. In order to insert locking pins 128 within sockets 118, sockets 118 may be spread apart slightly, thereby preloading haptics 124. One skilled in the art will recognize that no specific feature needs to be used to form hinge regions 126 as haptics 124 may be formed from a material and/or in such a configuration that haptics naturally flex in the manner of a hinge.

Once implanted in an eye, as one skilled in the art will recognize, contraction of capsular bag 300 will cause clasps 116 to collapse slightly, thereby causing compression

of optic 114. As optic 114 is compressed, hinge regions 126 allow optic 114 to vault anteriorly away from optic 112, with locking pins 128 pivoting within sockets 118.

As best seen in FIGS. 12 and 13, lens system 10 and 110 fills capsular bag 200 and 300, respectively, following removal of the natural lens. In order to remove the natural lens, an opening or rhexis is normally made in the anterior side of capsule 200 or 300. The opening contains rim or margin 212 or 312. During implantation of system 10 or 110, rim or margin 212 or 312 is inserted into socket 18 or 118 prior to the introduction of optic 14 or 114, respectively. Once optic 14 or 114 is installed in optic 12 or 112, locking pins 28 and 128 help to contain rim 212 or 312 within sockets 18 or 118, respectively, thereby maintaining a positive mechanical connection between capsular bag 200 and 300 and lens system 10 and 110, respectively. Contraction of capsular bag 200 or 300 will therefore be more directly translated into contraction of optics 12 and 112, respectively. In addition, the self-locking design of sockets 18 and 118 prevent capsular bag 200 and 300 from slipping out of sockets 18 or 118, respectively.

As best seen in FIGS. 15-21, lens system 410 of the present invention of the present invention generally consists of posterior optic 412 and anterior optic 414. Optic 412 is preferably formed in any suitable overall diameter or length, for example, around 12 millimeters, for implantation in the posterior chamber. Optic 412 preferably is made from a soft, foldable material that is inherently resistive to the formation of PCO, such as a soft acrylic. Optic 414 preferable is made from a soft, foldable material such as a hydrogel, silicone or soft acrylic. Optic 412 may be any suitable power, but preferably has a negative power. Optic 414 may also be any suitable power but preferably has a positive power. The relative powers of optics 412 and 414 should be such that the axial movement of optic 414 toward or away from optic 412 should be sufficient to adjust the overall power of lens system 410 at least one diopter and preferably, at least three to four diopters, calculation of such powers of optics 412 and 414 being within the capabilities of one skilled in the art as described above.

As best seen in FIGS. 15 and 16, optic 412 is generally symmetrical about optical axis 422 and contains a circumferential socket 418. As best seen in FIGS. 17-19, optic 414 contains a pair of hemispherical haptics 424 that are connected to optic 414 by hinge regions 426 and contain circumferential locking rib 428. As seen in FIG. 21, locking rib 428 is sized and shaped to fit within socket 418 on optic 412, thereby holding optic 414

firmly within optic 412 while allowing rotation of locking rib 428 within socket 418. Once implanted in an eye, as one skilled in the art will recognize, contraction of the capsular bag will cause compression of optic 414. As optic 414 is compressed, hinge regions 426 allow optic 414 to vault anteriorly away from optic 412, with locking rib 428 pivoting within socket 418.

As best seen in FIGS. 22-28, lens system 510 of the present invention of the present invention is similar to system 510 and generally consists of posterior optic 512 and anterior optic 514. Optic 512 is preferably formed in any suitable overall diameter or length, for example, around 12 millimeters, for implantation in the posterior chamber. Optic 512 preferably is made from a soft, foldable material that is inherently resistive to the formation of PCO, such as a soft acrylic. Optic 514 preferable is made from a soft, foldable material such as a hydrogel, silicone or soft acrylic. Optic 512 may be any suitable power, but preferably has a negative power. Optic 514 may also be any suitable power but preferably has a positive power. The relative powers of optics 512 and 514 should be such that the axial movement of optic 514 toward or away from optic 512 should be sufficient to adjust the overall power of lens system 510 at least one diopter and preferably, at least three to four diopters, calculation of such powers of optics 512 and 514 being within the capabilities of one skilled in the art as described above.

As best seen in FIGS. 22 and 23, optic 512 is generally symmetrical about optical axis 522 and contains a circumferential rib 528, which is similar to rib 428 in system 410. As best seen in FIGS. 24-26, optic 514 contains a pair of hemispherical haptics 524 that are connected to optic 514 by hinge regions 526 and contain circumferential socket 518. As seen in FIG. 28, locking rib 528 is sized and shaped to fit within socket 518 on optic 514, thereby holding optic 514 firmly within optic 512 while allowing rotation of locking rib 528 within socket 518. Once implanted in an eye, as one skilled in the art will recognize, contraction of the capsular bag will cause compression of optic 514. As optic 514 is compressed, hinge regions 526 allow optic 514 to vault anteriorly away from optic 512, with locking rib 528 pivoting within socket 518.

This description is given for purposes of illustration and explanation. It will be apparent to those skilled in the relevant art that changes and modifications may be made to the invention described above without departing from its scope or spirit.

We claim:

1. An intraocular lens, comprising:

- a) a first optic having a clasp with a socket;
- b) a second optic having at least one haptic, the haptic being connected to the second optic by a hinge region; and
- c) a locking pin located on the haptic, the locking pin sized and shaped to be received in the socket and thereby movably attach the second optic to the first optic.

2. The lens of claim 1 wherein the hinge region allows the second optic to vault away from the first optic in reaction to compression of the first optic.

3. The lens of claim 1 wherein the first optic and the second optic comprise a soft acrylic.

4. The lens of claim 1 wherein the second optic comprises a hydrogel.

5. The lens of claim 1 wherein the second optic comprises silicone.

6. The lens of claim 1 wherein the locking pin and socket are sized and shaped to retain an anterior capsular rhexis rim when the locking pin is installed within the socket.

7. The lens of claim 1 wherein the second optic has a circumference and the locking pin is located approximately 90° around the circumference from the hinge region.

1 8. A method of retaining a lens in a capsular bag, comprising the steps of:
2 a) providing a first optic having a clasp with a socket;
3 b) providing a second optic having at least one haptic, the haptic being
4 connected to the second optic by a hinge region the haptic containing a locking
5 pin, the locking pin sized and shaped to be received in the socket;
6 c) providing an opening in an anterior capsular bag, the opening having a rim;
7 d) placing the rim of the anterior capsule opening in the socket; and
8 e) inserting the locking pin into the socket so as to retain the rim in the socket
9 and movably attach the second optic to the first optic.

1 9. The lens of claim 8 wherein the hinge region allows the second optic to
2 vault away from the first optic in reaction to compression of the first optic.

1 10. The lens of claim 8 wherein the first optic and the second optic comprise a
2 soft acrylic.

1 11. The lens of claim 8 wherein the second optic comprises a hydrogel.

1 12. The lens of claim 8 wherein the second optic comprises silicone.

1 13. The lens of claim 8 wherein the locking pin and socket are sized and
2 shaped to retain an anterior capsular rhexis rim when the locking pin is installed within
3 the socket.

1 14. An intraocular lens, comprising:
2 a) a first optic having a clasp with a socket;
3 b) a second optic having at least one haptic, the haptic being hingedly
4 connected to the second optic; and
5 c) a locking pin located on the haptic, the locking pin sized and shaped to be
6 received in the socket and thereby movably attach the second optic to the first
7 optic.

1 15. The lens of claim 14 wherein the haptic allows the second optic to vault
2 away from the first optic in reaction to compression of the first optic.

1 16. The lens of claim 14 wherein the first optic and the second optic comprise a
2 soft acrylic.

1 17. The lens of claim 14 wherein the second optic comprises a hydrogel.

1 18. The lens of claim 14 wherein the second optic comprises silicone.

1 19. The lens of claim 14 wherein the locking pin and socket are sized and
2 shaped to retain an anterior capsular rhexis rim when the locking pin is installed within
3 the socket.

1 20. A method of retaining a lens in a capsular bag, comprising the steps of:

- 2 a) providing a first optic having a clasp with a socket;
3 b) providing a second optic having at least one haptic, the haptic being
4 hingedly connected to the second optic, the haptic containing a locking pin, the
5 locking pin sized and shaped to be received in the socket;
6 c) providing an opening in an anterior capsular bag, the opening having a rim;
7 d) placing the rim of the anterior capsule opening in the socket; and
8 e) inserting the locking pin into the socket so as to retain the rim in the socket
9 and movably attach the second optic to the first optic.

1 21. The lens of claim 20 wherein the haptic allows the second optic to vault
2 away from the first optic in reaction to compression of the first optic.

1 22. The lens of claim 20 wherein the first optic and the second optic comprise a
2 soft acrylic.

1 23. The lens of claim 20 wherein the second optic comprises a hydrogel.

1 24. The lens of claim 20 wherein the second optic comprises silicone.

1 25. The lens of claim 20 wherein the locking pin and socket are sized and
2 shaped to retain an anterior capsular rhexis rim when the locking pin is installed within
3 the socket.

1 26. An intraocular lens, comprising:

2 a) a first optic having a circumferential socket;

3 b) a second optic having at least one haptic, the haptic being connected to the
4 second optic by a hinge region; and

5 c) a circumferential locking rib located on the haptic, the locking rib sized and
6 shaped to be received in the socket and thereby movably attach the second optic to
7 the first optic.

1 27. The lens of claim 26 wherein the hinge region allows the second optic to
2 vault away from the first optic in reaction to compression of the first optic.

1 28. The lens of claim 26 wherein the first optic and the second optic comprise a
2 soft acrylic.

1 29. The lens of claim 26 wherein the second optic comprises a hydrogel.

1 30. The lens of claim 26 wherein the second optic comprises silicone.

1 31. The lens of claim 26 wherein the locking rib and socket are sized and
2 shaped to retain an anterior capsular rhexis rim when the locking rib is installed within the
3 socket.

1 32. An intraocular lens, comprising:

2 a) a first optic having a circumferential locking rib;

3 b) a second optic having at least one haptic, the haptic being connected to the
4 second optic by a hinge region; and

5 c) a circumferential socket located on the haptic, the socket sized and shaped
6 to receive the locking rib and thereby movably attach the second optic to the first
7 optic.

1 33. The lens of claim 32 wherein the hinge region allows the second optic to
2 vault away from the first optic in reaction to compression of the first optic.

1 34. The lens of claim 32 wherein the first optic and the second optic comprise a
2 soft acrylic.

1 35. The lens of claim 32 wherein the second optic comprises a hydrogel.

1 36. The lens of claim 32 wherein the second optic comprises silicone.

1 37. The lens of claim 32 wherein the locking rib and socket are sized and
2 shaped to retain an anterior capsular rhexis rim when the locking rib is installed within the
3 socket.

1/7

Fig. 1

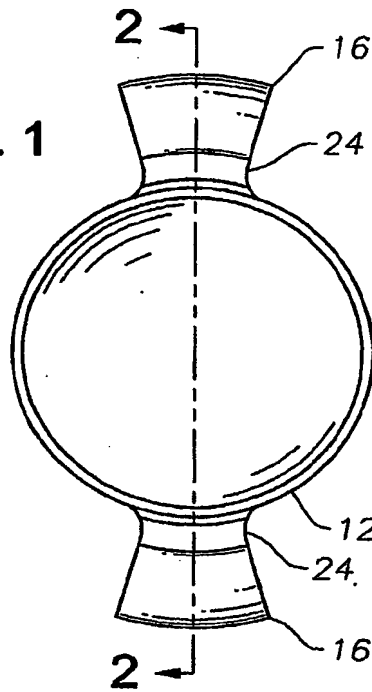


Fig. 2

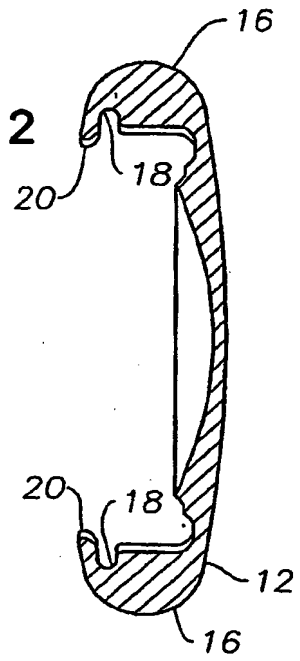


Fig. 3

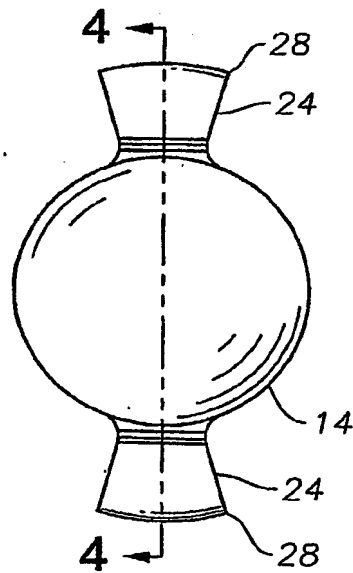


Fig. 4

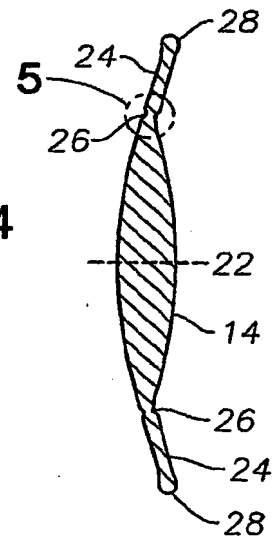
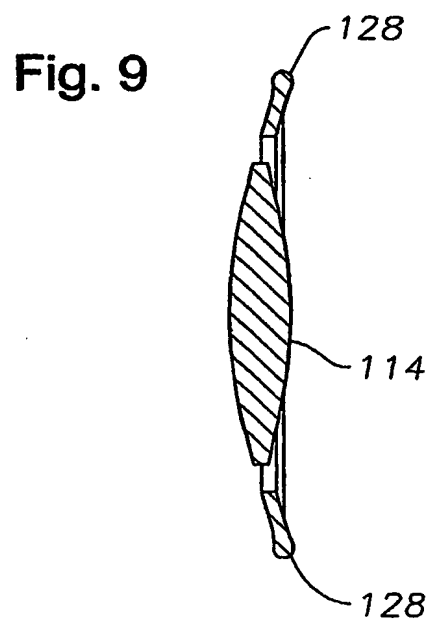
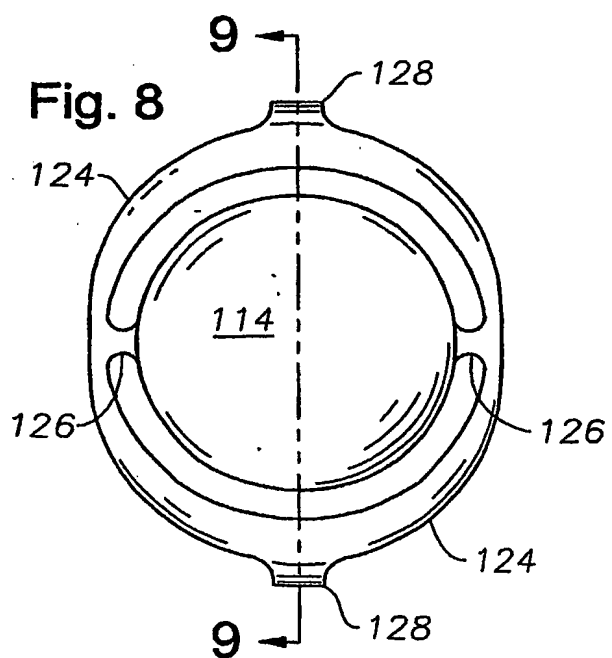
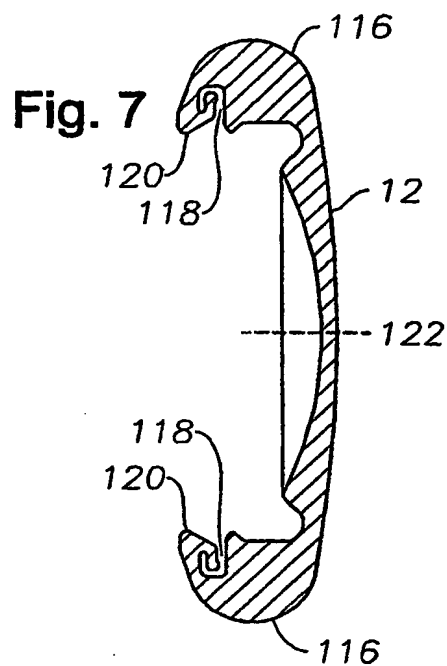
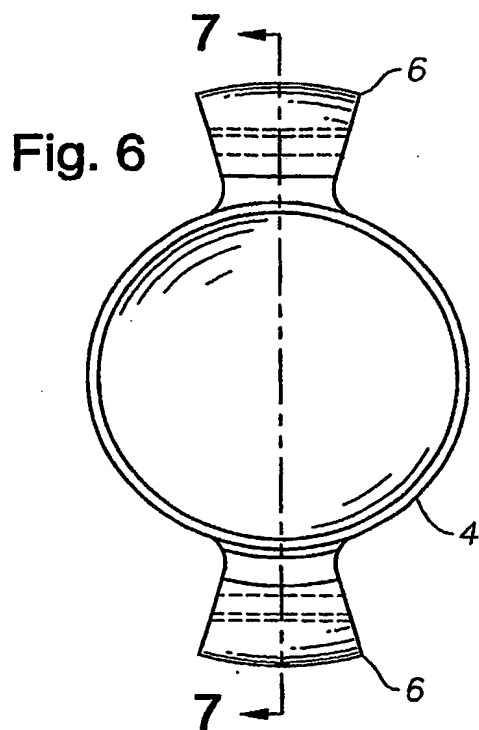


Fig. 5

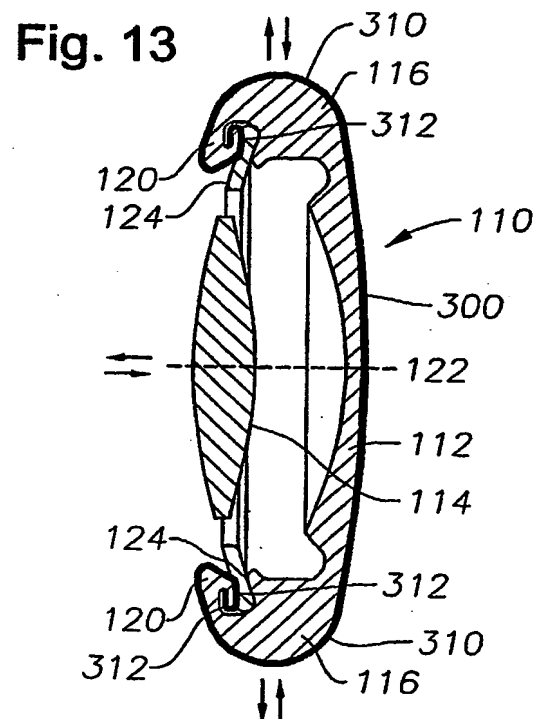
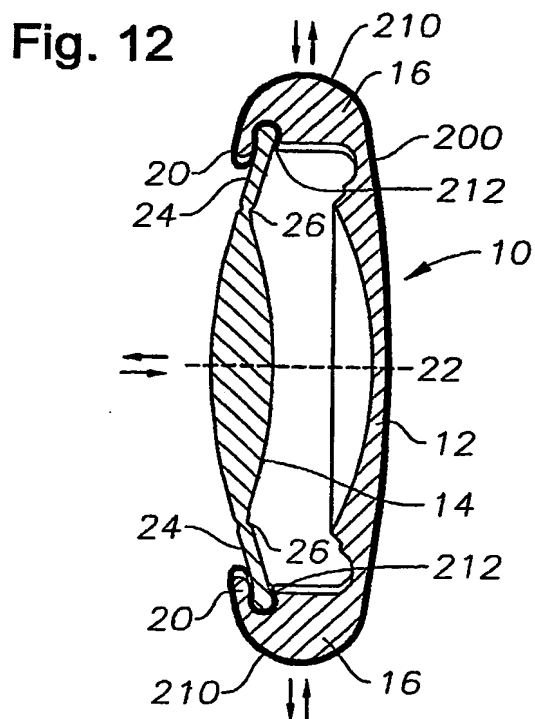
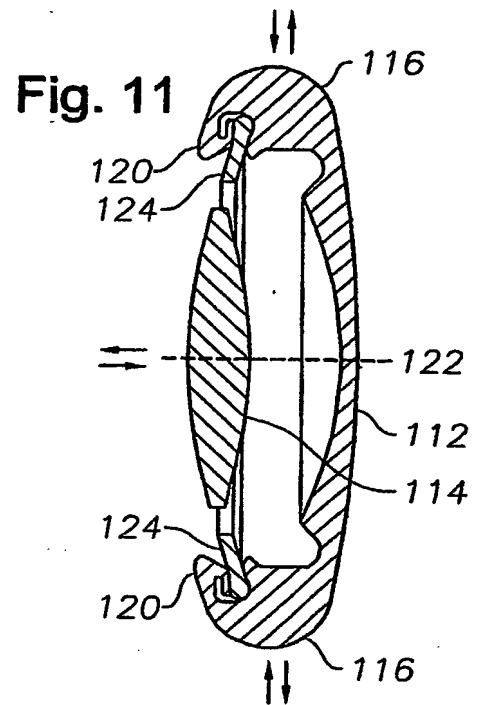
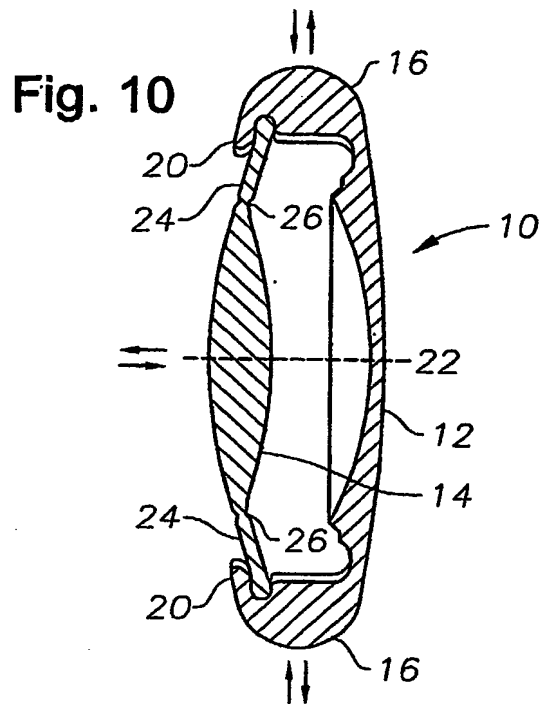


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Fig. 14

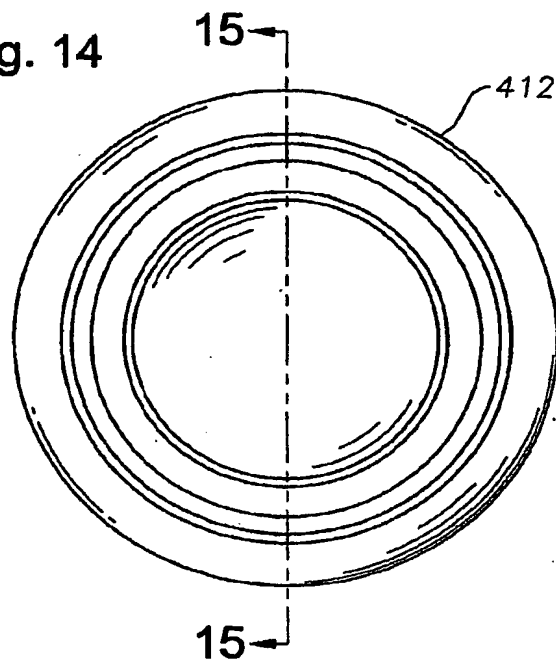


Fig. 15

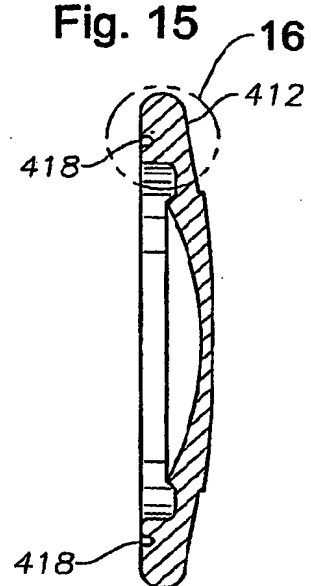


Fig. 16

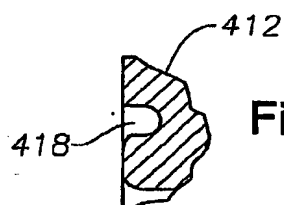


Fig. 17

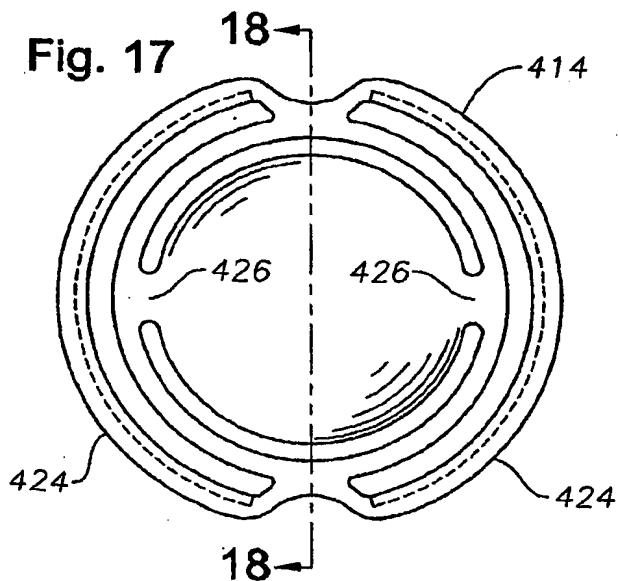
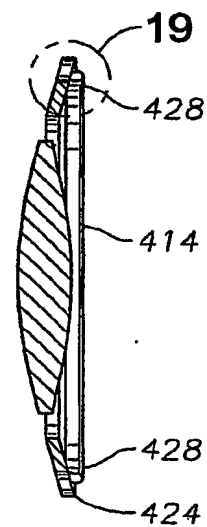


Fig. 18



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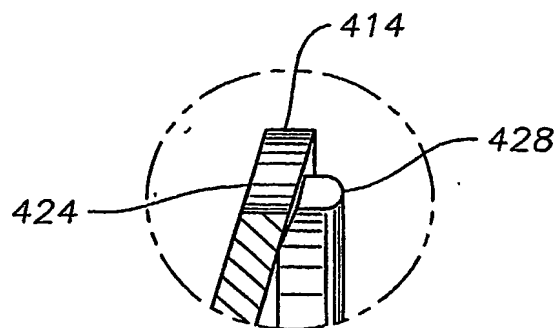


Fig. 19

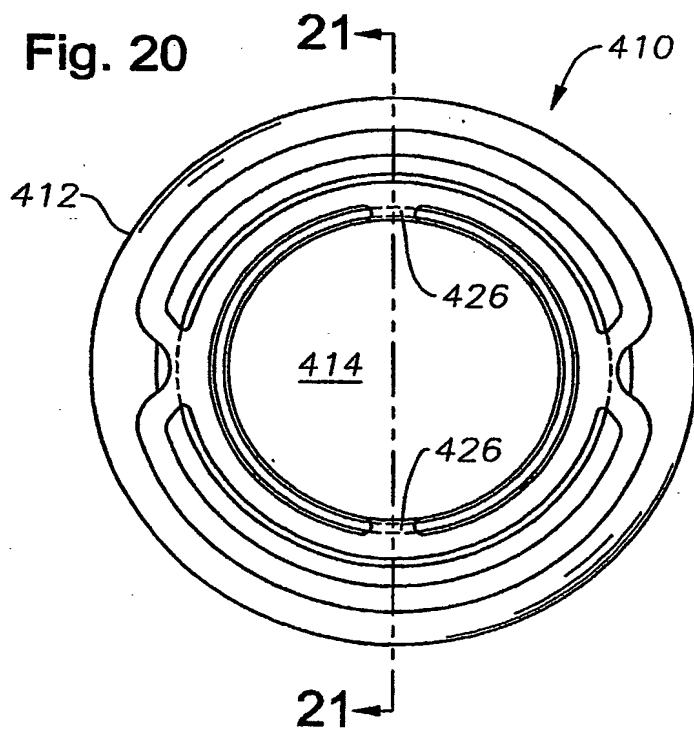


Fig. 20

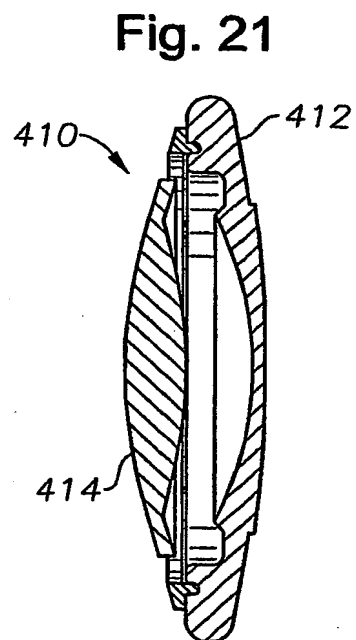


Fig. 21

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Fig. 22

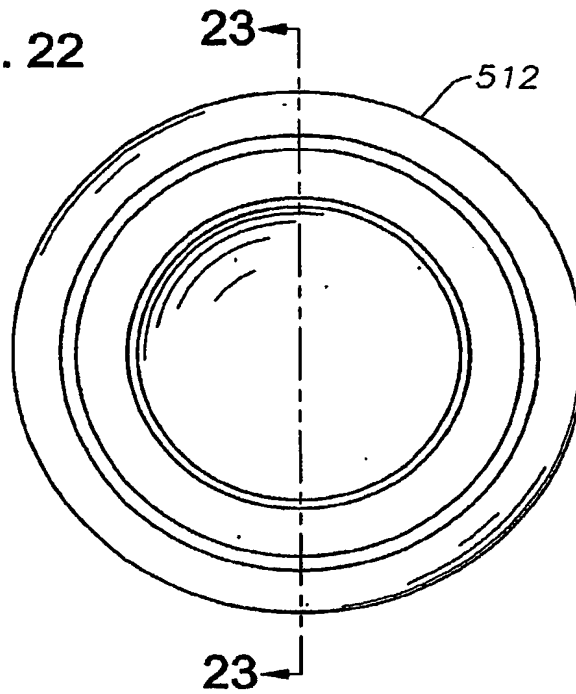


Fig. 23

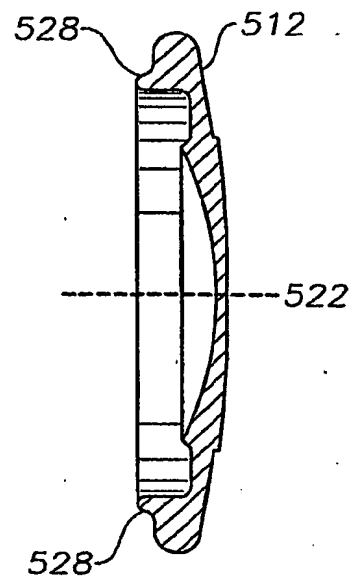


Fig. 24

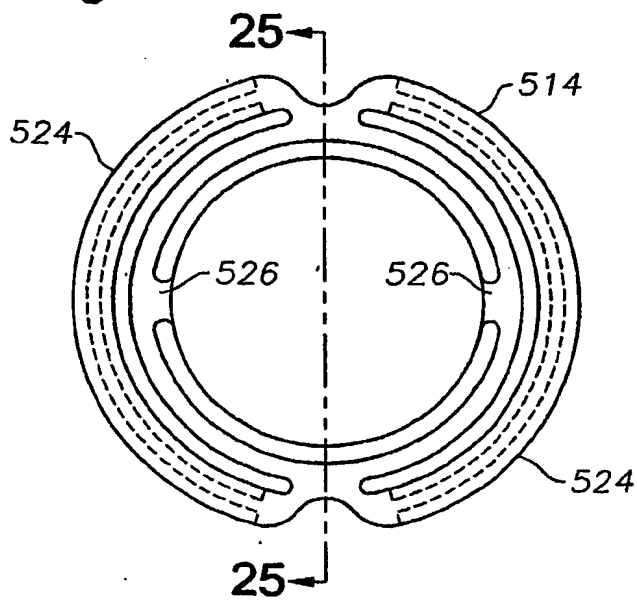
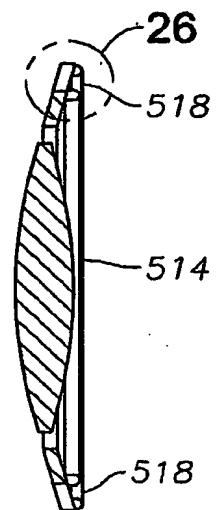


Fig. 25



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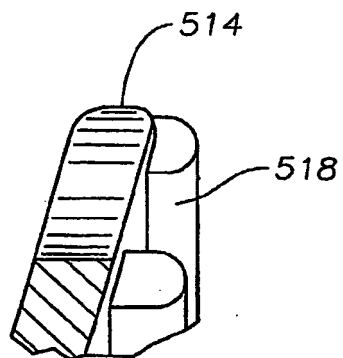


Fig. 26

Fig. 28

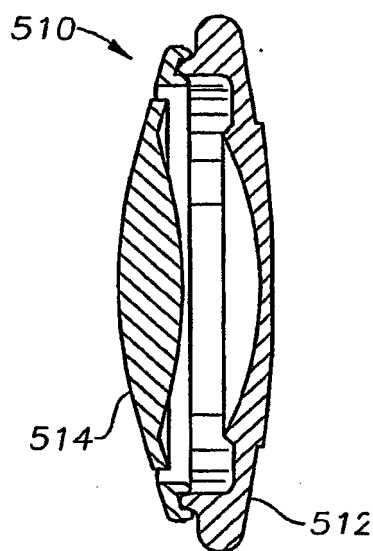
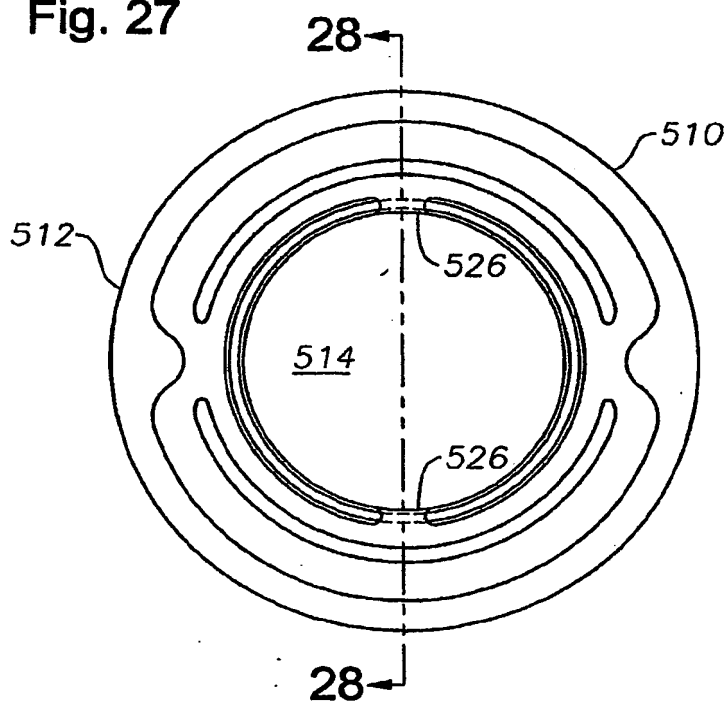


Fig. 27



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/07249

A. CLASSIFICATION OF SUBJECT MATTERIPC(7) : A61F 2/16
US CL : 623/6.32, 6.34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
U.S. : 623/6.32, 6.34

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US 6,454,801 B1 (Portney) 24 September 2002 (24.09.2002), columns 4-6, figures 1.	1-37
Y, P	US 6,488,708 B2 (Safarazi) 03 December 2002 (03.12.2002), columns 3-10 and figures 3.	1, 14, 26 and 32
Y	US 6,197,058 B1 (Portney) 06 March 2001 (06.03.2001), columns 2-13, and figures 1-9.	1, 14, 26, 32
Y	US 5,824,074 A (Koch) 20 October 1998 (20.10.98), columns 2-5 and figures 1 and 4.	1, 14, 26, 32

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Date of the actual completion of the international search

29 April 2003 (29.04.2003)

Date of mailing of the international search report

19 JUN 2003

Name and mailing address of the ISA/US

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